No. 89-243

In The Supreme Court of the United States October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY BRIEF

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Through several arguments first raised in its opposition brief, respondent Medtronic, Inc. (" Medtronic") attempts to misdirect this Court away from the straightforward, purely legal issue at hand. Medtronic also mischaracterized the only portion of the legislative history quoted by it. Medtronic commenced the quotation in the middle of the paragraph and omitted the key prefatory language that clearly negates Medtronic's argument. This reply brief is necessary to address these new issues and mischaracterizations.

Medtronic sets forth a wishful but erroneous "question presented" by substituting the words "regulated by the Federal Food, Drug and Cosmetic Act (FD&C Act)" for the operative statutory language of 35 U.S.C. §271(e)(1): "under a Federal law which regulates . . . drugs or veterinary biological products." The

plain meaning of the statute contradicts Medtronic's substitution. Congress expressly referred to the FD&C Act a few lines earlier in Section 271(e)(1). Congress would not have used different language — under a Federal law which regulates . . . drugs or veterinary biological products — to describe the *entire* FD&C Act later in the same provision.

Medtronic raises new arguments on the ripeness of this appeal and an alleged lack of record to support the widespread effect and importance of the Court of Appeals' decision.[1] Both of Medtronic's arguments are directly contrary to the positions that Medtronic argued before the Court of Appeals to obtain a full review of the Section 271(e)(1) legal *issue appealed by Medtronic.* Medtronic also states for the first time, incorrectly so, that one of the patents in suit, U.S. Patent 3,942,536 ("the '536 patent"), is no longer in issue (Brief in Opp., p. 3 n. 2).

Contrary to Medtronic's suggestion, this Court, not Congress, is the appropriate forum for correcting the erroneous interpretation of Section 271(e)(1) by the Court of Appeals. Medtronic's misdirection highlights the purpose of its entire opposition brief — an attempt to distract the Court from the sole legal issue before it.[2]

I. The Section 271(e)(1) Legal Issue Decided By The Court Of Appeals Is Ripe For Judicial Review

The question of ripeness for judicial review turns on "the fitness of the issues for judicial decision" and "the hardship to the parties of withholding court consideration." *Abbott Laboratories v. Gardner,* 387 U.S. 136, 149 (1967). Both of these factors strongly favor ripeness of the present issue for adjudication.

[1] Medtronic asserts that "petitioner will have another opportunity to present its arguments to the Federal Circuit on appeal from the final judgment in the case" (Brief in Op. pp. 19-20). If Medtronic is referring to Lilly's arguments relating to the single issue involved in Lilly's certiorari petition, Medtronic's argument is unfounded.

[2] Medtronic discusses at length the alleged, yet unproven features of its infringing devices, the features (albeit mischaracterized) of the devices of Lilly's subsidiary, the revenue that Lilly's subsidiary may receive, and the need for a full review of the FDA regulations for clinical trials. These allegations are of no controlling relevance and further demonstrate Medtronic's attempt to divert this Court's attention from the legal issue on appeal.

The issue presented on appeal undeniably is purely legal. It will not be clarified by further factual development. *Cf. Thomas v. Union Carbide Agricultural Products Co.,* 473 U.S. 568, 581 (1985); *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Development Comm'n,* 461 U.S. 190, 201 (1983).

Medtronic has admitted to the Court of Appeals that the Section 271(e)(1) issue on appeal requires no further factual development:

> The questions of law presented for review in this appeal do not depend on anything the lower court has yet to decide.

Supplemental Brief for Appellant Medtronic, Inc. on the standard of review, dated November 18, 1988, p. 6. For Medtronic, the ripeness of the legal issue at hand turns on whether Medtronic is the successful party on the issue at the time of the briefing. Its arguments are an attempt to misdirect this Court in order to avoid injunctive relief by delaying judicial review until the basic patent in suit, U.S. Patent Re.27,757 (the '757 patent), expires in October 1990. Unless the Court reviews the decision at this time, Lilly could lose forever its right to a complete injunction to prevent infringement of the '757 patent. The phrase "justice delayed is justice denied" applies here.

Lilly is irreparably harmed by a delay of consideration of Section 271(e)(1). The Court of Appeals' decision denies Lilly its exclusive patent position and a complete injunction against Medtronic. The district court concluded that, without an injunction, Medtronic would use "its current strength in the pacemaker industry to dominate the market involving devices for treating tachycardia and fibrillation" and that Lilly "will be irreparably harmed if Medtronic is not enjoined" (Pet. App. 37a).

The public interest would be served best by prompt resolution of Section 271(e)(1). To require the industries for medical devices, food additives, color additives and other nondrug, FDA-regulated products to proceed without certain dependable knowledge of whether Section 271(e)(1) applies to their products imposes a

considerable hardship. Without prompt judicial review, the industries involved could not be sure of the scope of their patent rights, which causes hardship on business planning.[3]

II. The Issue Presented Has Exceptional National Importance

Medtronic cannot credibly deny the importance of this case to the public. Medtronic already has advised the Court of Appeals that the Section 271(e)(1) issue is one "of exceptional importance to the public and to developers of medical products" (Suggestion of Medtronic, Inc. for a Hearing *In Banc*, p. 1).

The national importance of the legal issue presented is indisputable. Patent rights have been taken from patent holders in a vast range of federally-regulated industries. Over Medtronic's refusal to give consent, *amici curiae* have moved to file briefs in support of the petitioner. This activity confirms the exceptional importance of the issue raised in Lilly's petition. The Intellectual Property Owners, Inc.[4]; Bristol-Myers Co. and Zimmer, Inc.; Procter & Gamble Company; Pfizer, Inc. and Pfizer Hospital Products Group, Inc.; American Sterilizer Company; and Senator Orrin G. Hatch and Representative Carlos J. Moorhead have all filed motions for leave to file briefs *amicus curiae* expressing their views on the national importance of the issue presented and the clear error of the Court of Appeals' decision.

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[3] The interlocutory nature of the appeal of Section 271(e)(1) does not affect ripeness. *Cf. Northwest Airlines, Inc. v. Transport Workers Union of America*, 451 U.S. 77, 85-86 (1981) (case ripe to decide Title VII merits on interlocutory appeal); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986) (case ripe for a determination of constitutional issue on appeal of preliminary injunction); *Smith v. Vulcan Iron Works*, 165 U.S. 518, 525 (1897) (case ripe to decide merits on interlocutory appeal in patent case).

[4] The Board of Directors of the Intellectual Property Owners, Inc. includes two ex-Commissioners of the U.S. Patent and Trademark Office (Messrs. Donald W. Banner and William E. Schuyler, Jr.) and a "Who's Who" of patent counsel for U.S. companies. See the Appendix attached to Brief of Amicus Curiae Intellectual Property Owners, Inc. In Support of the Petitioner, p. 1a.

III. The Legislative History Contradicts Medtronic's Interpretation Of Section 271(e)(1)

In its only citation to the section's legislative history, Medtronic began the quotation in the middle of the paragraph (Brief in Op. pp. 11-12). Medtronic omitted key prefatory language from the House Committee report which immediately preceded the quotation relied upon. That prefatory language shows that the *limited experimental activity* exempted by Section 271(e)(1) is solely bioequivalency testing for generic drugs. It reads as follows:

> The purpose of sections 271(e)(1) and (2) is to establish that *experimentation with a patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that *this type of experimentation* is infringement.
>
> In *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.* __F.2d__ (Fed. Cir., April 23, 1984), the Court of Appeals for the Federal Circuit held that the *experimental use of a drug product* prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. [Medtronic's quotation commenced with the next word of this paragraph.]

H.R. Rep. No. 857, 98th Cong., 2d Sess. Part 1, at 45-46 (1984), *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2678-79 (emphasis added). Medtronic cannot cite a single legislative statement that contemplated experimental activity other than

in the narrow context of bioequivalency testing of generic drugs.[5]

Section 271(e)(1) is not a *quid pro quo* compromise accepted for the enactment of 35 U.S.C. § 156, the patent extension provisions of the Patent Act.[6] On the contrary, the two statutes are not coextensive. Section 271(e)(1) applies even during the original term of patents that have been extended. Section 271(e)(1) also applies to patents never extended. As is the case generally with the vast majority of medical device patents, Lilly has not received the benefits of a patent extension for the '536 patent. However, Lilly has lost its exclusive rights to the '536 patent under Section 271(e)(1) as construed by the Court of Appeals.[7]

The companion provisions to Section 271(e)(1), Sections 271(e)(2) and (e)(4), provide patent protections under certain circumstances for the patent holders of "drug" and "veterinary biological products" inventions (Pet. App. 62a-63a). No similar patent protections are provided for patent holders of "medical device", "food additive" or "color additive" inventions. If

[5] Medtronic could have avoided any alleged *de facto* extension of the patents in suit. Medtronic's expert trial witness, Mr. Paul Wylie, testified under oath that Medtronic can easily obtain FDA approval prior to patent expiration based on activities outside the United States that would not infringe the patents in suit. (Wylie Trial Test., Day 13, p. 161). *See also* 21 C.F.R. §814.15 (regulations permit FDA approval of medical devices based solely on foreign activities).

[6] The legislation that eventually led to enactment of 35 U.S.C. §156 had been before Congress since 1980, well before the 1984 *Roche* decision which prompted enactment of Section 271(e)(1). *See* S.2892, 96th Cong. 2d Sess. (1980). Medtronic erroneously implies that Congress enacted Sections 271(e)(1) and 156 for the same reasons.

[7] Contrary to Medtronic's arguments, the '536 patent is affected by the Court of Appeals' decision. The '536 patent expires in 1993. While Medtronic may have ceased temporarily its infringement of the '536 patent, Medtronic is permanently enjoined from infringing the '536 patent except for the exemption under Section 271(e)(1) as mandated by the Court of Appeals (District Court Order of June 28, 1989). Thus, the petitioner does have standing to raise the issue that Section 271(e)(1) is unconstitutional as applied to a patent that has not been extended (Brief in Op., p. 19 n. 16). Petitioner also raised on appeal that an expansion of Section 271 (e) (1) beyond bioequivalency testing for generic drugs raises a substantial corresponding constitutional "takings" issue. See Brief of Appellee Lilly before the Court of Appeals, pp. 26-28.

Congress had intended to include medical devices, food additives, and color additives within Section 271(e)(1), it is inconceivable that Congress would deprive the patent holders of these products the benefits of Sections 271(e)(2) and (e)(4).

CONCLUSION

The plain meaning of Section 271(e)(1) can be only that Section 271(e)(1) is limited to "drugs" or "veterinary biological products" as expressly identified therein. The statutory language "under a Federal law which regulates . . . drugs or veterinary biological products" cannot be interpreted to mean products "regulated by the entire Federal Food, Drug and Cosmetic Act" as urged by Medtronic. The decision below is clearly erroneous, and summary reversal is in order.

Respectfully submitted,

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